

2016-1814

**United States Court of Appeals
for the Federal Circuit**

SOFT GEL TECHNOLOGIES, INC.,

Appellant,

v.

JARROW FORMULAS, INC.,

Appellee.

*Appeal from the Patent Trial and Appeal Board of the
United States Patent and Trademark Office
In Re-Examination 95/002,396*

**REPLY BRIEF OF APPELLANT
SOFT GEL TECHNOLOGIES, INC.**

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TABLE OF ABBREVIATIONS AND CITATIONS

1. Citations to the Appendix are in the form Appx123, where page “123” of the Appendix is the cited page. Where appropriate, and in particular when citing to patent documents, column and line numbers for given pages are cited as Appx123 at 1:7-10, where column 1, lines 7-10 of page 123 are cited.
2. U.S. Patent No. 8,124,072 B2 is referred to as the “‘072 patent.”
3. Appellant Soft Gel Technologies, Inc. is referred to as “Soft Gel.”
4. Appellee Jarrow Formulas, Inc. is referred to as “Jarrow.”
5. The Patent Trial and Appeal Board of the United States Patent and Trademark Office is referred to as “Board” or “PTAB.”
6. Ubiquinone, also known as coenzyme Q10, is referred to as “coenzyme Q-10,” “coenzyme Q10,” “Q-10,” “Q10,” “CoQ10,” “CoQ-10,” or “ubiquinone.”
7. The prior art reference U.S. Patent No. 7,588,786 B2 to Khan et al. is referred to as “Khan” or “Khan ‘786.” Mansoor Khan, a named inventor of Khan ‘786, is referred to as “Dr. Khan.”
8. The prior art reference Nazzal, Sami Mahmoud, “Eutectic-Based Self-Nanoemulsified Drug Delivery Systems for Solid Oral Dosage Forms,” Graduate Dissertation dated August 2002, pages 1-289, is referred to as “Nazzal.” The author of Nazzal, Sami Nazzal, is referred to as “Dr. Nazzal.”

9. The prior art reference Motoyama et al., Patent Application Laid-Open Disclosure S57-42616, published Mar. 10, 1982, is referred to as “Motoyama.”

10. The prior art reference European Patent Publication 888,774 to Steele is referred to as “Steele.”

11. The prior art reference U.S. Patent No. 6,740,338 B1 to Chopra is referred to as “Chopra.”

12. The study published as A. Palamakula, M. Soliman, I.K. Reddy and M.A. Khan, “Preparation and In Vitro Characterization of Self-Nanoemulsified Drug Delivery Systems of Coenzyme Q-10 Using Chiral Essential Oil Components,” Pharmaceutical Technology, October 2004, is referred to as “Khan 2004.”

13. The prior art reference Fenaroli, G., “Fenaroli’s Handbook of Flavor Ingredients,” CRC Press (1975) is referred to as “Fenaroli.”

ARGUMENT

I. THE BOARD’S FAILURE TO ADDRESS THE CLAIMS AS AMENDED RESULTED IN A LEGALLY INCORRECT INTERPRETATION THAT HARMED SOFT GEL

It is undisputed that the Board erroneously interpreted the reviewed claims to require limonene rather than d-limonene. The error harmed Soft Gel because it expanded the scope of the claims beyond their broadest reasonable interpretation, giving them “a legally incorrect interpretation.” *In re Skvorecz*, 580 F.3d 1262, 1267-68 (Fed. Cir. 2009). Because the Board’s error affected its analysis of each rejection, they should all be reversed. *See, e.g., In re Man Mach. Interface Techs.*, 822 F.3d 1282, 1287 (Fed. Cir. 2016) (reversing anticipation rejection because reference did “not disclose the properly construed claim limitations...”).

A. The Decision Would Have Been Different Absent The Legal Error

Jarrow contends the result would have been the same had the Board considered the amended claims reciting d-limonene because “[a]ll of the evidence relied upon by the Board disclosed d-limonene, either explicitly or through the disclosure of natural lemon oil which contains only d-limonene.” Appellee’s Brief at 14. This is incorrect. At a minimum, one “cannot say with confidence that the Board would have reached the same conclusion in the absence of these errors.” *See In re Chapman*, 595 F.3d 1330, 1339-40 (Fed. Cir. 2010).

None of the main references expressly disclose d-limonene. Khan does not mention d-limonene. Nazzal does not mention d-limonene. Motoyama does not mention d-limonene. To the extent any of these references teach natural lemon oil, they do not also teach d-limonene because, contrary to Jarrow's contention, the evidence does not establish that natural lemon oil contains only d-limonene.

Jarrow cites a collection of Wikipedia pages from 2008 and argues that "[t]he evidence in the record established that lemons produce only one enantiomer, d-limonene." Appellee's Brief at 14-15 (citing Appx2081-2082).¹ The reliability of this Wikipedia evidence is suspect. *See Crispin v. Christian Audigier, Inc.*, 717 F. Supp. 2d 965, 976 n.19 (C.D. Cal. 2010) (noting risks of relying solely on Wikipedia). Moreover, Khan 2004 contradicts the Wikipedia evidence by teaching that limonene from citrus is not just d-limonene. *See* Appx656 ("Limonenes, monocyclic monoterpenes extracted from citrus fruits, are used as flavoring agents. They exist in two chiral conformations: R-(+)-limonene and S-(-)-limonene." (emphasis added)); *see also* Appx659. Even if one were to credit statements in the 2008 Wikipedia evidence, it is neither prior art to the '072 patent, nor evidence of

¹ On April 14, 2008, Soft Gel submitted a collection of Wikipedia pages during prosecution to illustrate the differences between terpinenes and limonene. *See* Appx2070; Appx2073; Appx2078-2081. Soft Gel did not rely on that evidence for the proposition that d-limonene is the only limonene in lemon oil, and it did not adopt every statement in those Wikipedia pages as its own. Accordingly, it is neither an admission nor binding on Soft Gel.

the knowledge of one of skill at the time the '072 patent was filed. To the contrary, Khan 2004 shows that even after the '072 patent was filed, those of skill in the art believed that both enantiomers of limonene were extracted from citrus fruit. *See* Appx656; Appx659.²

The Board's failure to address the claims as amended significantly expanded the claims beyond their broadest reasonable interpretation, thereby failing to afford the claims a legally correct interpretation. *See In re Skvorecz*, 580 F.3d at 1267-68. This hardly constitutes a "surface blemish[]" of the type complained of in the *Chemical Engineering* case cited by Jarrow. *See Chem. Eng'g Corp. v. Essef Indus., Inc.*, 795 F.2d 1565, 1572 (Fed. Cir. 1986). The Board's decision would have been different but for the error because the key prior art does not teach d-limonene explicitly or through disclosure of natural lemon oil. Thus, the error was harmful to Soft Gel and clearly affected Soft Gel's "substantial rights." The decision should therefore be reversed. *See In re Chapman*, 595 F.3d at 1339-40 ("[W]e conclude that these errors are harmful because they increase the likelihood that Chapman was erroneously denied a patent on grounds of obviousness. If the Board based its decision on a misunderstanding of Gonzalez, its conclusions regarding obviousness are called into question...Because we cannot say with

² Substantial evidence of record also does not support Jarrow's conclusion that d-limonene is the main constituent of lemon oil. *See infra.* at 17-21, 27-28.

confidence that the Board would have reached the same conclusion in the absence of these errors, we are persuaded they are indeed harmful.”); *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004).

B. Soft Gel Did Not Waive Its Right To Challenge the Board’s Error

Soft Gel appealed the rejection of the claims as amended, and contrary to Jarrow’s assertion, never waived the right to challenge the Board’s legal error. The record before the Board establishes that the claims under review were amended to recite d-limonene. The Examiner’s RAN *recited the claims as amended*. See Appx1397. The “Status of Claims” and “Status of Amendments” sections of Soft Gel’s appeal brief expressly stated that the claims were amended, and the “Summary of Claimed Subject Matter” discussed the claims as amended. Appx2002. Jarrow’s response accepted Soft Gel’s statements in this regard. See Appx2930. In addition, Soft Gel’s argument relied heavily on the failure of the prior art to teach *d-limonene*. See, e.g., Appx2014-2020 (heading: “Khan Does Not Anticipate Because It Contains No Disclosure Regarding d-Limonene...”); Appx2020 (heading: “One of Skill Would Not Understand Khan’s Lemon Oil to be d-Limonene or 90% d-Limonene”). Jarrow’s responsive argument similarly addressed the amended claims. See Appx2930-31 (“The rejected claims are directed to CoQ10 solubilized in d-limonene...”); Appx2932 (the claims “are directed to compositions comprising CoQ10 and a sufficient quantity of d-

limonene...”); Appx2938-2939; Appx2941-2943. At the hearing, the parties and Board also recognized that the claims require d-limonene. *See, e.g.*, Appx3441-3442; Appx3447; Appx3454; Appx3456; Appx3459.

The present situation is distinguishable from the activity constituting waiver in the cases cited by Jarrow. In *O2 Micro*, the appellant waived its right to appeal the language of an injunction that the appellant had proposed to the court. *O2 Micro Int’l, Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 449 F. App’x. 923, 934 (Fed. Cir. 2012). Similarly, in *Weinar*, the appellant waived its right to appeal the propriety of testimony that the appellant elicited during cross examination. *See Weinar v. Rollform, Inc.*, 744 F.2d 797, 805 (Fed. Cir. 1984). Unlike Soft Gel’s erroneous recitation of patent claims in an appendix to a brief, the appellants in *O2 Micro* and *Weinar* promoted affirmative positions and/or evidence. Soft Gel did not propose the Board’s order and did not elicit testimony to which it later objected. Consequently, all of the rejections should be reversed.

II. THE ANTICIPATION REJECTIONS BASED ON NAZZAL MUST BE REVERSED

A. The Board Legally Erred in Shifting the Burden to Soft Gel Because Melting Q10 in Lemon Oil as Disclosed in Nazzal is Not “Identical or Substantially Identical” to Dissolving Q10 in d-Limonene

Jarrow acknowledges that the PTO must show a “sound basis for believing that the products of the applicant and the prior art are the same” before shifting the

burden to the applicant to show they are not. *See* Appellee’s Brief at 39 (quoting *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (emphasis added)). Jarrow also acknowledges that in order to shift the burden, the Board must put forth “sufficient factual findings, such that it can reasonably infer” the products of the applicant and the prior art are the same. *Id.* at 40 (citing *Howmedics Osteonics Corp. v. Zimmer, Inc.*, 640 F. App’x. 951, 958 (Fed. Cir. 2016) (emphasis added)). Indeed, only when the claimed invention and prior art are “identical or substantially identical” and the Examiner has established that the prior art “read identically on the limitations of the [subject] claims,” can the burden of proof be shifted to the applicant to show that the prior art does not necessarily or inherently possess the characteristics of the claimed subject matter. *In re Best*, 562 F.2d 1252, 1254-55 (C.C.P.A. 1977) (emphasis added); *In re Mousa*, 479 F. App’x. 348, 353 (Fed. Cir. 2012) (emphasis added).

Jarrow contends the Board properly shifted the burden to Soft Gel because it made “sufficient factual findings to reasonably infer that Khan/Nazzal’s solution of CoQ10 and d-limonene was the same as the claimed solution.” Appellee’s Brief at 40. However, Jarrow fails to address the following evidence presented by Soft Gel that contradicts any reasonable inference that Nazzal’s lemon oil is “identical or substantially identical” to the claimed d-limonene:

- Nazzal does not mention d-limonene;

- There is no evidence in the record as to the d-limonene content of the lemon oil actually used by Nazzal;
- The limonene content of lemon oil can vary considerably;
- The percentage of limonene in citrus peel oil that is d-limonene is variable;
- The Board acknowledged in a related case that “Lota provides evidence that d-limonene is not always the main constituent of lemon peel oil,” reversed its finding that d-limonene is “the main constituent of lemon peel oil,” and acknowledged that it cannot be concluded that d-limonene is “necessarily present in amounts higher than any other constituent”;
- Dr. Khan followed up his lemon oil experiments with a separate study of d-limonene.

See Appellant’s Brief at 20-23. Jarrow’s only response to this evidence – that it constitutes “attorney argument” or “rank speculation” – completely misses the mark. *See* Appellee’s Brief at 40-42. These are facts supported by the record. In light of this evidence, it cannot be reasonably inferred that the claimed d-limonene is “identical or substantially identical” to Nazzal’s lemon oil.

Jarrow also fails to address the following evidence presented by Soft Gel that contradicts any reasonable inference that Nazzal's melting of Q10 is "identical or substantially identical" to dissolving Q10:

- The Board acknowledged that the Examiner cited no support for the finding that melting and dissolving are "closely related;"
- The District Court recognized a distinction in Khan between melting and dissolving;
- The Board recognized a "key difference" between melting and dissolving.

See Appellant's Brief at 24-26.

Regardless, the Board's analysis is flawed. The Board acknowledged that the District Court distinguished "melting" from "dissolving" and found that the District Court's findings regarding Khan are applicable to Nazzal. Appx16-17. Yet the Board concluded that the District Court's finding "does not exclude there from being similarities between the two processes" because both involve energy changes. Appx21. However, the Board found that many physical changes and chemical reactions are accompanied by changes in energy. *See* Appx17-18, FF8. Based on the Board's conclusion, any such physical changes and chemical reactions – vaporization or combustion for instance – would be "closely related" to melting or dissolving if the energy change helped overcome intermolecular

attractive forces. *See id.* But “[t]he inherent result must inevitably result from the disclosed steps.” *In re Montgomery*, 677 F.3d 1375, 1380 (Fed. Cir. 2012). Thus, even if the Board is correct that melting and dissolving are “closely related” because they both involve energy changes, substantial evidence contradicts any reasonable inference that they are “identical or substantially identical.”

Because melting Q10 in lemon oil as disclosed in Nazzal is not “identical or substantially identical” to solubilizing (which, as used in the claims, means “dissolving”) Q10 in d-limonene as required by the claims, it was legal error for the Examiner and Board to shift the burden to Soft Gel to prove Nazzal’s lemon oil does not “necessarily or inherently” contain “a sufficient quantity of d-limonene suitable to solubilize” Q10. *In re Best*, 562 F.2d at 1254-55. The rejection based on Nazzal should be reversed.

B. Nazzal Examples I and II Form an Emulsion Prior to Introduction Into an Aqueous Environment

Nazzal does not anticipate because it teaches an emulsion, which is excluded from the claims of the ‘072 patent. Jarrow interprets Nazzal (and Khan) as teaching that SNEDDS becomes an emulsion only once it is introduced into an aqueous environment like the gut. As discussed in Soft Gel’s opening brief, however, Nazzal clearly teaches that the melted oily mix of essential oil and Q10 should be combined with surfactants and other ingredients to form an emulsion *before the formulation is introduced into the gut*:

The eutectic-based self-nanoemulsified drug delivery system (SNEDDS) of CoQ₁₀ was prepared as follow [sic]: CoQ₁₀ and lemon oil at a ratio of 1:1 were accurately weighed into screw-capped glass vial and *melted* in water bath at 37°C. Cremophor EL and Capmul MCM-C8 were added to the oily mix at a final concentration of 26.9% w/w each. The resultant emulsion was mixed with a stirring bar until a transparent solution of SNEDDS was obtained. The SNEDDS were then allowed to cool at ambient temperature for 24 hrs until a viscous paste was obtained. Nanoemulsion adsorbed granular material was obtained from a mixture of SNEDDS paste, copolyvidone (Kollidon VA 64), maltodextrin (Glucidex IT 12), and microcrystalline cellulose (Avicel) at a ratio of 0.11/0.13/0.56/0.2 respectively.

Appx290-291 (emphasis added); *see also* Appx322; Appx281; Appx325; Appx493 at 2:55-61, 2:35-39. Khan includes similar disclosures. *See* Appx498 at 11:62-12:6.

Jarrow concedes that Nazzal and Khan expressly refer to “Example II” as an “emulsion.” *See* Appellee’s Brief at 37; Appx3475-3476 (“Now, I agree that Khan puts the word emulsion there...”). Faced with this express disclosure, Jarrow attempts to confuse the issues by suggesting that Example I and Example II are distinct disclosures, urging the Court to disregard Example II in favor of Example I. However, it is indisputable that both Example I and Example II are based on the same preliminary process for creating SNEDDS, namely: (1) mixing Q10 and essential oil together in a glass vial; (2) melting the mixture to form an oily melt; (3) adding surfactant; and (4) stirring the mixture with a bar. *See, e.g.,* Appx495 6:43-50 and Appx281 (Example I); Appx498 at 11:61-12:1 and Appx290 (Example II). Jarrow conceded this similarity at the hearing before the Board. *See*

Appx3467-3469; Appx3474-3475. The only apparent difference is that one goes into a capsule and the other into a tablet.

Nazzal/Khan clearly teach that an emulsion is created when surfactant is added in step (3) of the preliminary process identified above. *See* Appx290-291 and Appx498 at 11:62-12:6 (referring to the “resultant emulsion” created upon addition of surfactant to the oily mix). Although this particular statement was expressly made in the Example II discussion, it applies equally to Example I since the preliminary processes of the two examples are the same. In any event, Example I further includes its own express teachings of an emulsion absent any suggestion of an aqueous environment. *See* Appx325 (“Due to the limited solubility of CoQ₁₀ in fixed oils and triglycerides...the melting point depression method using essential oils provides an attractive alternative for the preparation of an emulsified formulation.”); Appx331 (“A preparation could be made at which body temperature is used to melt a system comprising essential oil, CoQ₁₀ and an emulsifier when the essential oil is added in an amount sufficient to lower the melting temperature of CoQ₁₀ to or below 37°C.”); Appx331 (“Due to limited solubility of CoQ₁₀ in surfactants the use of Cremophor EL as a model emulsifier not only induces crystallization of CoQ₁₀ in the cooled supersaturated mixture but also may delay or retard re-melting the system at higher temperatures.”) (emphasis

added in all); *see also* Appx495 at 6:57-60; Appx495-496 at 6:65-7:2; Appx496 at 7:36-40.

Nothing in Example I expressly states that the SNEDDS is not an emulsion prior to being introduced into an aqueous environment. Accordingly, even to the extent Example I suggests that an emulsion is formed when SNEDDS is introduced into an aqueous environment, Nazzal/Khan teach that an emulsion is also formed when surfactant is added to the oily mix. *See* Appeal 2015-004072, Reexamination Control 95/002,411, Decision on Appeal at 9 (P.T.A.B. Aug. 31, 2015) (quoting Appx498 at 11:62-12:6) (“while melting is used to form an oily mix of Q10 and lemon oil...subsequently when the oily mix is combined with a carrier...an emulsion is formed.” (emphasis added)); *see also id.* at 9-10 (“Even if the lemon oil contains sufficient d-limonene to ‘dissolve’ the Q10 upon melting in Khan ‘786, the limitations of claim 1 are still not met because the subsequent steps of Khan ‘786 involve emulsification which is excluded by the claim.” (emphasis added)). Nazzal/Khan suggest no reason that Q10, lemon oil and surfactant form an emulsion when they are mixed in Example II, but do not form an emulsion when the same steps are followed in Example I.

Moreover, neither the Examiner’s definition of emulsion, nor the portion of Khan cited by Jarrow, support Jarrow’s contention that “emulsifiers do not create an emulsion themselves,” or that emulsifiers “require the presence of another

liquid, such as water, to create an emulsion. Appellee’s Brief at 35; *cf.* Appx1398 (defining “emulsion” as a “substantially permanent mixture of two or more liquids which do not normally dissolve in each other...The suspension is usually stabilized by small amounts of additional substances known as emulsifiers.”); Appx493 at 2:52-55 (“A SNEDDS contains an isotropic mixture of oil, surfactant, co-surfactant and drug, which forms a fine oil-in-water emulsion when introduced into an aqueous medium under gentle agitation.”). The presence of an emulsifier signifies an emulsion.

In further effort to avoid the express teaching of an emulsification in Example II, Jarrow contends that the teachings of Example II are “internally inconsistent and ambiguous.” Appellee’s Brief at 38. However, Nazzal/Khan *unambiguously* state that addition of surfactant to the oily mix of Q10 and essential oil created a “resulting emulsion.” This statement is also not “internally inconsistent.” Nazzal teaches that the oily mix plus surfactant constitute an “emulsion,” which, *when mixed with a stirring bar*, ultimately forms a “transparent solution.” *See* Appx290; Appx498 at 11:61-12:1. There is nothing internally inconsistent about this. Nazzal further teaches that some emulsions and microemulsions are transparent. *See* Appx236; Appx282; Moreover, because Nazzal teaches that Q10 has limited solubility in surfactants, *see* Appx331, the mixture of Q10 and surfactant represents immiscible liquids, which is consistent

with the Board's conclusion that an "emulsion" requires two immiscible liquids. Appx12.

Substantial evidence does not support the Board's conclusion that Nazzal's four-part composition is not an emulsion excluded by the claims. The rejection should be reversed.

C. Nazzal Teaches Melting Q10 Rather Than Dissolving Q10 in a "Sufficient Quantity of d-Limonene"

Nazzal expressly teaches melting point reduction as an alternative way to liquefy Q10 precisely because it is difficult to dissolve:

Due to the limited solubility of CoQ-10 in fixed oils and triglycerides...**the melting point depression method** using essential oils **provides an attractive alternative** for the preparation of an emulsified formulation.

Appx325 (emphasis added); *see also* Appx199; Appx16, FF 5; Appx495 at 6:57-60. Consistent with this disclosure, Khan's claim 1 requires a sufficient amount of essential oil "**to reduce the melting point** of ubiquinone to 37 ° C. or below, **and thereby solubilize** the ubiquinone comprised in the orally administered dietary supplement at or below body temperature." Appx502 at Claim 1 (emphasis added). "Preparation of Coenzyme Q₁₀ (CoQ₁₀), presents an additional challenge in the development of an oral formulation because of its poor solubility." Appx199. Thus, Nazzal melted Q10 because he could not dissolve it. Indeed,

Jarrow concedes that in Khan and Nazzal, Q10 is liquefied by melting, and that the liquid Q10 is “thereby solubilized.” Appellee’s Brief at 21, 26.

Jarrow contends that Dr. Nazzal’s declaration “explains that when the CoQ10 is melted to a liquid, it is solubilized in the essential oil.” *Id.* at 26. However, Dr. Nazzal clearly distinguishes melting and dissolving. He testified that he melted CoQ10 because he could not dissolve it. *See* Appx1151-1152 at ¶ 3. He further testified that only after the Q10 is melted in lemon oil, can it then be “dissolved or solubilized in additional excipients...” Appx1152 at ¶ 6; *see also* Appx1157 at ¶ 15 (“[Khan] describes and teaches that mixing CoQ10 with a suitable amount of a volatile essential oil would melt the CoQ10...which could then be mixed with additional ingredients...such that the solubility of the CoQ10 in the entire multi-component system can be maintained...”).

Jarrow’s argument relies on the implicit assumption that as soon as Q10 is melted into liquid form, it is completely miscible (and therefore dissolved) in the lemon oil. *See, e.g.*, Appellee’s Brief at 22; Appx3489-3490. Dr. Nazzal’s declaration suggests otherwise: first it is melted, and then it is dissolved when additional ingredients are added. In fact, Jarrow concedes that the oil and Q10 create an “oily phase,” which suggests the liquids are immiscible. *See* Appellee’s Brief at 22. This is consistent with the Board’s definition of an emulsion. *See* Appx12.

Indeed, paragraph 4 of Dr. Nazzal's declaration – upon which Jarrow relies – states that Khan teaches “that a sufficient amount of volatile essential oil reduces the melting point of CoQ10...to thereby liquefy and solubilize the CoQ10...” Appx1152 at ¶ 4 (emphasis added). It is precisely this language that the District Court pointed to in reaching the conclusion that Khan distinguishes between melting and dissolving. *See Jarrow Formulas, Inc. v. NOW Health Grp., Inc.*, No. CV 10-8301 PSG (JCx), 2012 WL 3186576, at *9 (C.D. Cal. Aug. 2, 2012).

1. Soft Gel Did Not Waive An Argument That the District Court's Judgment is Dispositive

Jarrow contends that Soft Gel waived any argument that the District Court's judgment is dispositive because Soft Gel did not raise the argument until its reply brief before the Board. On July, 28, 2014, Soft Gel argued the District Court's findings in its opening brief. *See* Appx1998 (cover page dated July 28, 2014); Appx2010-2011. But the District Court's judgment did not become binding until it was affirmed by this Court on October 8, 2014. *See Jarrow Formulas, Inc. v. NOW Health Grp., Inc.*, 579 F. App'x. 995 (Fed. Cir. 2014), *aff'g* 2012 WL 3186576 (C.D. Cal. Aug. 2, 2012). The argument was not waived because it could not have been raised any sooner.

Jarrow's additional contention that the District Court judgment has no bearing on this proceeding because “the issues litigated in the two proceedings are

entirely different” is incorrect for the reasons previously identified by Soft Gel. *See* Appellant’s Brief at 34, n.6.

Jarrow failed to address the District Court’s conclusion, and has failed to identify any “concrete evidence in the record” to support the conclusion that since Q10 melts in lemon oil, it also necessarily dissolves in lemon oil. *See In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001). Because substantial evidence of record does not support the Board’s conclusion that Nazzal inherently discloses that Q10 is dissolved in d-limonene, the rejection should be reversed.

D. Substantial Evidence Does Not Support the Finding That Nazzal’s Lemon Oil Contains a “Sufficient Quantity of d-Limonene Suitable to Solubilize” Q10 Because The Evidence is In Conflict Regarding the Quantity of d-Limonene in Lemon Oil

It is undisputed that Nazzal does not expressly disclose d-limonene. In addition, Dr. Khan’s subsequent study investigating d-limonene and its ability to reduce the melting point of Q10 demonstrates that Nazzal’s lemon oil *did not* contain a sufficient quantity of d-limonene suitable to dissolve Q10; otherwise, there would have been no reason to pursue the study. *See* Appx656. Apart from Khan’s own subsequent work, there is no direct evidence in the record regarding the limonene or d-limonene content of the lemon oil actually used by Nazzal/Khan.

The record evidence is in hopeless conflict regarding the quantity of d-limonene in lemon oil generally. *See Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487-88 (1951) (substantial evidence review involves examination of the

record as a whole). Lota discloses that the amount of *limonene* in citrus peel oils can vary greatly, and may be less than 40%. Appx1259-1260. The evidence further shows that the percentage of limonene in citrus peel oil that is d-limonene is also variable. Appx1110-1111. Even assuming – for the sake of discussion only – that the limonene in the Lota sample contained 100% d-limonene, there is no record evidence to suggest that lemon oil with 40% limonene contains a “sufficient quantity of d-limonene suitable to solubilize” Q10. The Board admits as much: “even if the amount of limonene present in the lemon oil/Q10 mixture described in Nazzal is less than the lower limit of 36% by weight calculated by the Examiner...there still must be evidence that such lower amounts would or would not dissolve Q10.” Appx23. There is no such evidence.

Indeed, the Board recently acknowledged that “Lota provides evidence that d-limonene is not always the main constituent of lemon oil peel.” Appeal 2015-004072, Reexamination Control 95/002,411, Decision on Rehearing at 11 (P.T.A.B. August 12, 2016). The Board further determined that it cannot be concluded that d-limonene is “necessarily present in amounts higher than any other constituent.” *Id.* at 3. Instead, the Board determined that d-limonene is merely “a characteristic component of lemon oil.” *Id.*

Jarrow complains that “of the nineteen tests conducted by Lota on various species and cultivars of lemon oil, only one revealed 38.1% d-limonene.”

Appellee's Brief at 32. As an initial matter, Jarrow incorrectly suggests that Lota references d-limonene and that the "d-limonene was the largest constituent" in the Lota sample cited by Soft Gel. Lota references limonene; the sample cited by Soft Gel contained 38.1% limonene. Regardless, inherency "'may not be established by probabilities or possibilities.'" *White v. H.J. Heinz Co.*, 640 F. App'x. 930, 933 (Fed. Cir. 2016) (quoting *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991)). "The inherent result must inevitably result from the disclosed steps." *In re Montgomery*, 677 F.3d at 1380. Absent inevitability, inherency does not follow, even where there is a high likelihood that a prior art method will result in the claimed invention. *See Glaxo, Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995) (even though the defendant's experts reproduced the prior art method "thirteen times and each time they made [the claimed] crystals," the patentee's chemists twice produced different crystals from the same method, thereby precluding inherency. (emphasis added)). Thus, Lota's sample containing only 38.1% limonene is sufficient to preclude inherency.

Dr. Nazzal's testimony is hardly probative of the content of d-limonene in lemon oil. Citing no evidence, Dr. Nazzal testified that lemon oil "is reported to be 90% d-limonene." Appx1156-1157 at ¶ 14 (emphasis added). Accordingly, his conclusion that "[b]ecause lemon oil is 90% d-limonene, the observed depression in CoQ10's melting temperature can be attributed to d-limonene" is mere

conjecture. *See id.*; *see also* Appx717 (noting similar opinions given by Dr. Nazzal in the District Court action “are not based on Dr. Nazzal’s first-hand experiences conducting the background experiments...”). In any event, consistent with the repeated teachings in Khan/Nazzal, Dr. Nazzal’s statement clearly indicates that melting – **not dissolving** – of Q10 is attributed to d-limonene.

Jarrow contends that during prosecution of the related ‘583 patent, “Soft Gel submitted Fenaroli to the PTO, and argued Fenaroli’s teachings with respect to d-limonene in order to obtain allowance of the claims in the related ‘583 patent,” so Soft Gel is bound by those teachings. Appellee’s Brief at 28. However, Fenaroli does not even mention d-limonene in its lemon oil discussion. *See* Appx1624. Accordingly, there are no “teachings with respect to d-limonene” in Fenaroli to which Soft Gel can be bound. Similarly, Jarrow contends that during the same prosecution “Soft Gel argued to the PTO that “the limonene in lemon oil contains only d-limonene.” However, as discussed in footnote 1, *supra*, Soft Gel provided Wikipedia evidence to illustrate the differences between terpinenes and limonene. *See* Appx2073; Appx2078-2081. Soft Gel did not rely on that evidence for the proposition that d-limonene is the only limonene in lemon oil, and it did not adopt every statement in the Wikipedia evidence as its own. Moreover, Khan 2004 teaches that d-limonene is not the only limonene enantiomer in natural lemon oil. *See supra*, at 2; Appx656; Appx659.

Jarrow's approach to the evidence is to disregard (or misinterpret) Lota and Khan 2004 in favor of other evidence. However, "[c]are must be taken to avoid hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.'" *In re NTP, Inc.*, 654 F.3d 1279, 1299 (Fed. Cir. 2011) (quoting *Grain Processing Corp. v. American-Maize Prods. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988)). Here, the evidence does not "make clear" that Khan's lemon oil contained a "sufficient quantity of d-limonene suitable to solubilize" CoQ-10. *See Cont'l Can*, 948 F.2d at 1268. The evidence is conflicting, at best, with Jarrow failing to address the most probative evidence – Khan's subsequent work. Jarrow improperly relies "on hindsight reasoning" to cherry pick among conflicting references in order "to piece together elements to arrive at the claimed invention." *In re NTP*, 654 F.3d at 1299. The selected evidence is simply insufficient to meet the high burden of establishing anticipation by inherency.

E. Soft Gel Did Not Have a Fair Opportunity to Respond to the Non-Record Textbook Evidence, and The Board's Resulting Conclusion Based on That Evidence is Flawed

Jarrow contends that it was proper for the Board to take judicial notice of a non-record textbook for "further support" and to "fill in the gaps" of the Examiner's finding that melting and dissolving are "closely related." Appellee's

Brief at 42-43. However, Jarrow overlooks the fact that the Board acknowledged the Examiner cited no support for that finding. Thus, the Board did more than attempt to provide further support or fill in the gaps – it attempted to create support for the Examiner’s otherwise unsupported finding. Until this appeal, Soft Gel had no opportunity to respond to the non-record evidence. In addition, because the PTO’s finding was previously unsupported by any evidence, Soft Gel’s opportunity to respond to the finding was limited.

Regardless, the Board’s analysis based on the non-record textbook is fatally flawed. *See supra* at 8-9. Thus, the Board failed to present any “concrete evidence in the record” to support the conclusion that since Q10 melts in lemon oil, it also necessarily dissolves in lemon oil.

III. ONE OF SKILL WOULD NOT HAVE BEEN MOTIVATED TO SUBSTITUTE D-LIMONENE INTO MOTOYAMA’S INVENTION WITH ANY REASONABLE CHANCE OF SUCCESS

Motoyama dissolved Q10 using carvone-containing oils. It does not mention d-limonene, limonene, or lemon oil. Nazzal and Khan melted Q10 using volatile oils. Neither mentions d-limonene; Khan does not mention limonene; Nazzal contains only a limited disclosure suggesting further investigation of limonene. To reach the conclusion that Motoyama’s carvone-containing oil could be substituted with Nazzal/Khan’s volatile lemon oil to achieve a sufficient amount of d-limonene to dissolve Q10 requires several leaps of logic.

Even within the realm of Khan's and Nazzal's own invention, there was no reasonable expectation that limonene – let alone d-limonene – would reduce the melting point of Q10. Accordingly, Nazzal suggested further investigation of limonene for these purposes. *See* Appx456. Consistent with this suggestion, Khan's subsequent study examined whether d-limonene could reduce the melting point of Q10. Appx656. As discussed in Soft Gel's opening brief, given this evidence, it is an even further stretch to find that one of skill would have been motivated to substitute d-limonene into Motoyama's invention with any reasonable chance of success. *See* Appellant's Brief at 42-44.

Rather than focusing on the critical evidence of Nazzal's suggestion to further investigate limonene and Khan's subsequent study of d-limonene, the Board relied on multiple erroneous mischaracterizations of fact discussed in on pages 45-46 of Soft Gel's opening brief. The Board also improperly used the claims to navigate the prior art and make the several leaps of logic necessary to reach the conclusion that Motoyama's carvone-containing oil could be substituted with Nazzal/Khan's volatile lemon oil to achieve a sufficient amount of d-limonene to dissolve Q10. *See In re NTP*, 654 F.3d at 1299.

Jarrow similarly avoids the critical evidence raised by Soft Gel, and substantially defers to the Board's tangled web of logical leaps. In addition, as discussed below, Jarrow's analysis of the evidence is flawed, and in some

instances outright misleading. Given the Board's legal error, and the lack of substantial evidence to support its findings, the obviousness rejections based on all combinations involving Motoyama, Khan, and Nazzal must be reversed.

A. Jarrow's Analysis of The Evidence Is Flawed and Misleading

Jarrow's suggestion that Fenaroli teaches "that the form of limonene present in natural lemon oil is d-limonene" (Appellee's Brief at 49) is incorrect. Fenaroli does not even mention d-limonene in its lemon oil discussion. *See* Appx1624. Moreover Khan's 2004 study teaches that limonene from citrus is not just d-limonene. *See supra* at 2-3, 20.

The alleged testimony of Dr. Dash, Soft Gel's expert in the District Court action involving Khan, does not support the conclusion that it would have been obvious to substitute Motoyama's carvone-containing oil with d-limonene from the lemon oil of Khan/Nazzal. As an initial matter, Jarrow cites the District Court's discussion of Dr. Dash's opinions in its summary judgment order, and not the testimony itself. *See* Appellee's Brief at 50 (citing Appx721). Without the benefit Dr. Dash's entire testimony, the significance of the District Court's discussion of that testimony is suspect.

In any event, Dr. Dash's opinions in the District Court case addressed whether Motoyama anticipates or renders Khan obvious, not whether it would have been obvious to substitute Khan's lemon oil for Motoyama's carvone-containing

oils to achieve a sufficient amount of d-limonene to dissolve Q10. *See* Appx718-722. The claims of the Khan patent under review in that case were not limited to d-limonene, as they are here. *See* Appx502. Even accepting Dr. Dash's alleged opinion that it would have been "obvious to use or obvious to try lemon oil" in the Motoyama's invention, Dr. Dash offers no opinion regarding whether one of skill would have been motivated to substitute d-limonene into Motoyama's invention with any reasonable chance of success.

Jarrow attempts to minimize Khan 2004 by suggesting that the study reached the same result as the Khan patent. *See* Appellee's Brief at 52-53. However, the graph in Figure 4 of Khan does not even contain data for a 90:10 combination of Q10 and lemon oil, as Jarrow suggests. *See* Appx483 at Fig. 4. Moreover, Khan 2004 concluded that d-limonene did not reduce the melting point of Q10. *See* Appx659 ("Thus, the reduction in peak time for the binary mixture of CoQ with S-(-)-limonene [(l-limonene)] could be a result of eutectic formation, whereas the R-(+)-limonene [(d-limonene)] did not affect the CoQ melting point.").

Jarrow contends that Soft Gel presents only attorney argument and not any "any evidence in the record" regarding the lack of motivation to combine. *See* Appellee's Brief at 53. The disclosures of the prior art references themselves and subsequent studies by the same inventors of those references are evidence in the record, and there is no stronger evidence to demonstrate that one of skill would not

have been motivated to substitute the volatile lemon oil of Nazzal/Khan for Motoyama's carvone-containing oil with any reasonable chance that the combination would achieve a sufficient amount of d-limonene to dissolve Q10.

B. The Board's Erroneous Statement that Nazzal "Expressly Suggested" Evaluating d-Limonene is Not Supported by Substantial Evidence

In reaching its obviousness conclusion, the Board repeatedly relied on the erroneous statement that Nazzal "expressly suggested" evaluating d-limonene. *See* Appellant's Brief at 45-46. Jarrow downplays this error, suggesting that it was reasonable for the Board to infer that "Nazzal's suggestion to evaluate limonene referred to d-limonene." Appellee's Brief at 54. Just like the "evidence" presented by Jarrow to suggest a motivation to combine, the "evidence" presented by Jarrow in support of this argument (*see id.* at 54-56) is flawed. First, Soft Gel did not admit during prosecution of the related '583 patent that "lemon oil contains approximately 90% d-limonene and that citrus oils (e.g. lemon oil) contain only d-limonene." *See supra* at 2-3, 20. Second, Jarrow's contention that the only form of limonene that occurs in nature is d-limonene is contradicted by Khan 2004. *See id.* Third, although the Board found in the related examination that the error regarding its interpretation of Nazzal did not change its decision on obviousness, that decision is incorrect for the same reasons stated herein and has been appealed to this Court.

C. The Board's Erroneous Finding That d-Limonene is the Main Constituent of Lemon Oil Is Not Supported By Substantial Evidence

The Board recently reversed a finding that d-limonene is “the main constituent” of lemon oil. Appeal 2015-004072, Reexamination Control 95/002,411, Decision on Rehearing at 11 (P.T.A.B. Aug. 12, 2016). In doing so, the Board acknowledged that “Lota provides evidence that d-limonene is not always the main constituent of lemon oil peel.” *Id.* (citing Appx1260). Because the Board’s obviousness rejection in this case was based on the erroneous finding that d-limonene is “the main constituent of lemon oil,” substantial evidence does not support the Board’s finding of obviousness.

Jarrow contends that the Board’s finding that d-limonene is “the main constituent of lemon oil” – which the Board itself has acknowledged was erroneous – is supported by substantial evidence. As with its other arguments, Jarrow points to the same flawed and misleading evidence already discussed herein, namely: Fenaroli, the Wikipedia evidence, and the fact one sample out of nineteen in Lota revealed 38.1% d-limonene. These arguments fail for the reasons stated above. *See supra* at 2-3, 20. Jarrow further contends that despite acknowledging its erroneous finding in the related reexamination, the Board did not change its obviousness determination. However, the Board’s obviousness

determination in that case is incorrect for the same reasons stated herein and has been appealed to this Court.

IV. SOFT GEL CHALLENGED ALL REJECTIONS BASED ON THE COMBINATION OF KHAN, NAZZAL AND MOTOYAMA

Jarrow suggests that Soft Gel's brief did not challenge the Board's rejection of (1) dependent claims 4, 11 and 21 as obvious in view of Khan, Nazzal, Motoyama, Patent Owner's admission on Motoyama, and Steele as evidenced by Fenaroli, Duetz, Mondello and IARC; and (2) dependent claims 12 and 22 as obvious in view of Khan, Nazzal, Motoyama, Patent Owner's admission on Motoyama, and Davidson as evidenced by Fenaroli, Duetz, Mondello and IARC. This is not true. Soft Gel's opening brief specifically asks the Court to reverse the Board's rejection of claims 1-24 as obvious in view of Motoyama, Khan, Nazzal, "and the other cited art." *See* Soft Gel's Opening Brief at 48. The fundamental analysis of every obviousness rejection involving the combination of Motoyama, Khan and Nazzal is the same. Accordingly, like the Board, Soft Gel addressed all of these rejections with a single discussion *See* Appx27-33. All obviousness rejections based on Motoyama, Khan, Nazzal and the other cited art must be reversed.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

For the reasons stated herein, and in Soft Gel's opening brief, the Court should reverse (1) all of the rejections on the grounds that the Board failed to

analyze the claims as amended; (2) the rejection of claims 1-3, 6-10, 14-20 and 24 as anticipated by Nazzal; (2) the rejection of claims 1-24 as obvious in view of Motoyama, Khan, Nazzal, and other cited art; (3) the rejection of claims 4, 11 and 21 as obvious based on Nazzal and Steele; and (4) the rejection of claims 12 and 22 as obvious based on Nazzal and Motoyama. In addition, the Court should reverse, or, at a minimum remand, the Examiner's rejections based on Ground 1 (anticipation by Khan), Ground 2 (obviousness based on Khan and Steele), and Ground 3 (obviousness based on Khan and Motoyama), which the Board acknowledged but failed to address in its written analysis.

Dated: November 14, 2016

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PROOF OF SERVICE

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